Standard Operating Procedure –

Common Data Element Curation under the caBIG™ Program

This cover sheet controls the layout and components of the entire document.

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Note: This document will be issued for training on the Issue Date. The document will become available for use to trained personnel on the Effective Date. Before using this document, make sure it is the latest revision. Access the caBIG™ website to verify the current revision.

Revision History

Revision	Date	Author	Change Reference	Reason for Change
1.0	09/19/2005	SOP Working Group	N/A	Initial release.
2.0	10/30/2006	BP SIG/SOP WG	All pages	Annual update.

1. Purpose

This Standard Operating Procedure (SOP) describes the process by which new Common Data Elements (CDEs) are created to support clinical research under the caBIG™ Program.

2. Scope

This SOP will be used for the development and maintenance of all CDEs for clinical research covered under the caBIG™ Program and sponsored by the National Cancer Institute (NCI).

3. Requirements

3.1 All CDEs are created in the Cancer Data Standards Repository (caDSR) and loaded into the clinical data management application to support or enable the conduct of clinical research under the caBIG program.

3.2 All CDEs created for use in the clinical data management application should be reviewed for correctness and available for reuse across the environment.

3.3 Before a CDE can be moved to the "released" workflow status and imported into the clinical data management application, verification must be received from Clinical Study Team that the data requirements have been implemented correctly and the CDE is complete.

3.4 The creation of new CDEs to support data requirements for clinical data capture is an iterative process. Final verification of the correctness and 'fit for purpose' for new CDEs that will be loaded into the clinical data management application is the responsibility of caDSR Curator and Clinical Study Team.

3.4 When data collection requirements call for the creation of a new CDE, this SOP will be followed.

4. References/Regulations/Guidelines

Section	SOP Number	Title
4.1	N/A	CDISC Glossary
4.2	N/A	SOP WG Glossary of Terms
4.3	N/A	ICH E9
4.4	N/A	ICH E6 Good Clinical Practice
4.5	CR-005	SOP for Application's Standards Library Maintenance
4.6	IT-004	SOP for Electronic Loading of CDEs

5. Roles & Responsibilities

Role	Responsibility
Study Designer	• Review list of existing CDEs in the clinical data management application and the NCI Enterprise Vocabulary Service (EVS) prior to requesting a new CDE.
Application's Standards Librarian	• Initiate requests for new CDEs. • Work with the caDSR Curator and the CDE Loader Technician to manage the loading of new CDEs.
caDSR Curator	• Work with the application's Standards Librarian to review the request to construct a new CDE. • Prepare the file for loading new CDE into the clinical data management application.
CDE Loader Technician	• Load the newly created CDE into the appropriate application.
Clinical Study Team	• Responsible for following the blind and unblinding requirements as defined by the protocol. • Execute unblinding of research subjects, when applicable (Statistician, Principal Investigator, or the Clinical Research Nurse), per established and documented standard clinical processes for clinical research trial execution. • Provide input to the statistician on the protocol and Statistical Analysis Plan (SAP). • Provide the necessary clinical information or interpretation input on SAEs captured during the conduct of the clinical research trial, including input on coding of events. • Respond to requests from DSMB for safety issues, as appropriate. • Completes patient's eligibility checklist. • Reviews content of CRF against protocol requirements • Reviews physical layout of CRF and provides comments • Signs off version of final CRFs
Study Coordinator	• Work with the Study Designer and the application's Standards Librarian to review and select CDEs in support of protocol requirements.

6. Attachments

This SOP will be used in conjunction with the following attachments. These attachments must be used by all research sites conducting clinical trials under the caBIG™ Program and can be customized by individual research sites to accommodate format and content in accordance with local guidelines and/or requirements.

Title	Description
1) Procedure Description for Common	This document provides instructions for creating CDEs. It

Title	Description
Data Element (CDE) Curation	provides step-by-step guidance to assure that all CDEs are prepared and managed in a consistent manner.
2) Process Flow for Creating New CDEs	This document identifies the workflow activities, by role, for the steps identified in the Procedure for Creating New CDEs for use in the caBIG™ Program.